K100762

FUJIFILM
Fujifilm Medical Systems, USA

JUL 15 2010

510(k) Summary for FDR D-EVO Flat Panel Detector

Date: March 16, 2010

Contact Person:

Name:	Debbie Peacock
Title:	Regulatory Coordinator
Telephone:	(203) 602-3774
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Identification of Device:

Proprietary/Trade Name:	FDR D-EVO (DR-ID600)
Classification Name:	Solid State X-ray Imager (Flat Panel/Digital Imager)
Classification:	Panel: Radiology
CFR Section:	21 CFR 892.1650
Product Codes:	90 MQB
Common Name:.	Flat Panel Digital Detector

I. INDICATIONS FOR USE

The FDR D-EVO flat panel detector system is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications wherever conventional film /screen or CR systems may be used. The FDR D-EVO is not intended for mammography.

II. DEVICE DESCRIPTION

FDR D-EVO flat panel detector is an indirect-conversion amorphous silicon (a-Si) portable flat panel detector (FPD) utilizing GOS (Gadolinium OxySulfide) as a scintillator. FDR D-EVO detector has Fuji's unique Irradiation Side Sampling system, delivering high image quality.

D-EVO's 14x17" standard cassette size affords it the ability for use as a retrofit in any analog bucky and/or as an additional panel with fixed digital radiography systems, allowing a quick conversion to digital X-ray technology. The D-EVO features a detachable power source that enables easy positioning within the radiographic room within an upright bucky, table or as a free cassette. Data captured via operator console is sent electronically to the Fujifilm FDX Console to be displayed on the monitor.

III. SUMMARY OF STUDIES

Fujifilm's D-EVO Flat Panel Detector successfully completed internal and international IEC testing requirements.

In addition, Fujifilm performed an image quality reader study on 30 image pairs comparing the FDR D-EVO system with the cleared Fujifilm Carbon XL-2. Three board certified radiologists reviewed the images as described below.

Analysis Methodology:
All images must be deemed to be of diagnostic capability. In addition, the study will be considered a success if at least 90% of the scores from the D-EVO system are greater than or equal to –1.

Results:
All images were deemed to be of diagnostic capability, in addition, all readers satisfied the success criteria with 100% of the D-EVO image scores greater than or equal to –1. Test Protocol and Results are enclosed as Attachments H and I.

IV. SUBSTANTIAL EQUIVALENCE

The Fujifilm FDR D-EVO Flat Panel Detector is substantially equivalent to the following currently cleared device:

Predicate Device	510(k) #
Canon CXDI-55G	K091435
Carestream DRX-1	K090318
Fujifilm Carbon XL-2	K042023

The proposed and predicate devices utilize similar technology and materials, comparable safety and effectiveness features, and are similar in design and construction. The Indications for Use and labeling are virtually the same, or similar and our labeling contains the required Cautions, Warnings and Contraindications consistent to those required for similar cleared devices..

The FDR D-EVO and the predicate Canon CXDI-55G detector are both portable, digital indirect conversion, amorphous silicon (a-Si), wired GOS detectors used for the same application, to image general radiographic examinations, excluding mammography. The Carestream DRX-1 detector is a portable, digital indirect conversion, amorphous silicon (a-Si), wireless GOS detectors used for the same application, to image general radiographic examinations, excluding mammography. All systems produce digital images which can be sent to hardcopy printers, softcopy diagnostic workstations and/or stored in archive.

Fujifilm Carbon XL-2 reads the x-ray image from cassette based photostimuable phosphor plates and converts it to a digital image. The FDR D-EVO FPD is used to directly capture digital X-ray images. Both systems use an acquisition workstation to display the acquired images and transmit them via network connection for diagnostic viewing and printing.

V. CONCLUSION

The FDR D-EVO Flat Panel Detector is substantially equivalent to the cleared predicate detectors and conforms to applicable medical device safety standards

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Debra A. Peacock
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FUJIFILM Medical Systems, USA Inc.
419 West Avenue
STAMFORD CT 06902

AUG 23 2013

Re: K100762
Trade/Device Name: FDR D-EVO (DR-ID 600) Flat Panel Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: May 17, 2010
Received: May 18, 2010

Dear Ms. Peacock:

This letter corrects our substantially equivalent letter of July 15, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100762

Device Name: FDR D-EVO (DR-ID 600) Flat Panel Detector

Indications for Use:

The FDR D-EVO flat panel detector system is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications wherever conventional film /screen or CR systems may be used. The FDR D-EVO is not intended for mammography, fluoroscopy, tomography, and angiography applications.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100762